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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,235	07/22/2004	Malgorzata Anna Kisielow	1-32330A/FMI	9191

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NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
SAJJADI, FEREYDOUN GHOTB	
ART UNIT	**PAPER NUMBER**
1633	

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/502,235	KISIELOW ET AL.	
	Examiner	Art Unit	
	Fereydoun G. Sajjadi	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 3-8, 10-11, 13-14, 16-19 and 21 have been amended, by the amendment dated July, 22, 2004.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-12, 14-20 drawn to a method of expressing a desired isoform of a gene in a mammalian cell, comprising the introduction into said cell, of at least a partially double stranded (ds) RNA having at least 95% sequence identity to a common sequence shared by two or more isoforms of said gene and also introducing into said cell a vector expressing the said desired isoform of a gene; and a kit comprising reagents that include the said ds RNA and said vector for said method.

Group II, claims 13, 23, drawn to a method of assigning function to a desired isoform of a gene, comprising introducing into a mammalian cell, a partially double stranded (ds) RNA having at least 95% sequence identity to a common sequence shared by two or more isoforms of said gene and also introducing into said cell a vector expressing the said desired isoform of a gene; identifying phenotypes of said cell in the presence and absence of said desired isoform.

Group III, claim 21, drawn to a mammalian cell exhibiting isoform-specific expression of a gene achieved by a method comprising the introduction into said cell, of at least a partially double stranded (ds) RNA having at least 95% sequence identity to a common sequence shared by two or more isoforms of said gene and also introducing into said cell a vector expressing the said desired isoform of a gene.

Group IV, claim(s) 22, drawn to a method of treating a disease comprising administering to a subject a nucleic acid that is at least a partially ds RNA having at least 95% sequence identity to a common sequence shared by two or more isoforms of a gene and also introducing into said subject a desired isoform of a gene.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

37 CFR 1.475 (c) states:

"If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

37 CFR 1.475 (d) states:

"If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and §1.476(c)."

In view of 37 CFR 1.475 (c) and 37 CFR 1.475 (d), Group I is considered the main invention that is drawn to the first method, first mentioned in the claims of the application (i.e. a method of expression an isoform-specific gene product) and the first recited invention drawn to other categories related thereto (i.e. kit for practicing the invention of Group I).

Groups II-IV claims are drawn to multiple distinct processes of use and multiple distinct products that do not share the same inventive concept as in Group I. The claimed inventions of Groups II-IV recite distinct materials and/or method steps that are neither required nor recited in the claimed invention of Group I, and thus have their own technical features, e.g. determination of phenotypic alterations in a mammalian cell (Group II), a mammalian cell exhibiting isoform-specific expression (Group III), a method of treatment (Group IV) and a method for achieving isoform-specific gene expression (Group I). Further, each of the groups has a technical feature not required for the other groups. For example, the method of Group I does not require the morphological alterations of the method of Group II and may produce a cell exhibiting no phenotypic alteration and thus be structurally and functionally distinct from the mammalian cell of Group II. The mammalian cell of Group III may be produced by a separate method that does not require the particulars of the method of claim I. Further, the product resulting from the method of Group I may be distinct from the mammalian cell of Group III. The invention of Group IV is drawn to a method of treating a disease comprising administering to a subject both an interfering RNA and a desired isoform of a gene. The treatment method of Group IV does not require the mammalian cell of Group III, or the experimental method for determining function, as recited in Group II. Finally, the method of Group IV may be carried out by variations in the method of Group I.

Each invention is directed to a distinct goal, which comprises the use of separate products or methods in order to achieve its respective and intended objective. Thus, it follows from the preceding analysis that the claimed inventions listed as Groups I-IV do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical features for the reasons set forth above.

Applicant should note that if Group II is elected, claim 13 should be written in independent form and in such language as to be directed to a cell containing undesired isoforms of a gene product.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

A specifically named single species of a mutant isoform of a gene as recited in claim 12; a specifically named single species of cell line as recited in claim 15.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 6, 11, 12, 14, 20 and 21, and claims dependent therefrom correspond to all the species listed above.

The following claim(s) are generic: 12 and 15.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: As the technical features (oncogenic, apoptotic, tumor suppressive, inflammation inductive, angiogenic, HeLa, PC3, MDA-MB-231 and MCF-7) linking the members do

not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature or function, the requirement for unity of invention is not fulfilled.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, restriction for examination purposes as indicated is proper.

Thus, it would be unduly burdensome for the examiner to search all the claimed inventions being sought in the pending claims.

Applicant is advised that the reply for this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst Dianiece Jacobs, whose telephone number is **(571) 272-0532**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fereydoun G. Sajjadi whose telephone number is **(571) 272-3311**. The examiner can normally be reached Monday through Friday, between 7:00 am-4:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on **(571) 272-0731**. The fax phone number for the organization where this application or proceeding is assigned is **(571) 273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

For all other customer support, please call the USPTO Call Center (UCC) at **(800) 786-9199**.

Fereydoun G. Sajjadi, Ph.D.
Examiner, USPTO, AU 1633

DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER